

Medtronic and Medical Device Industry- Mitigating Electromagnetic Interaction

Dan Dummer, Ph.D.
Engineering Director - Reliability Test
Medtronic CRDM

November 2010

Objective and outline

Describe electromagnetic compatibility of Medtronic pacemakers and other devices and Medtronic's basic EMC strategy as relevant to the auto industry

Outline:

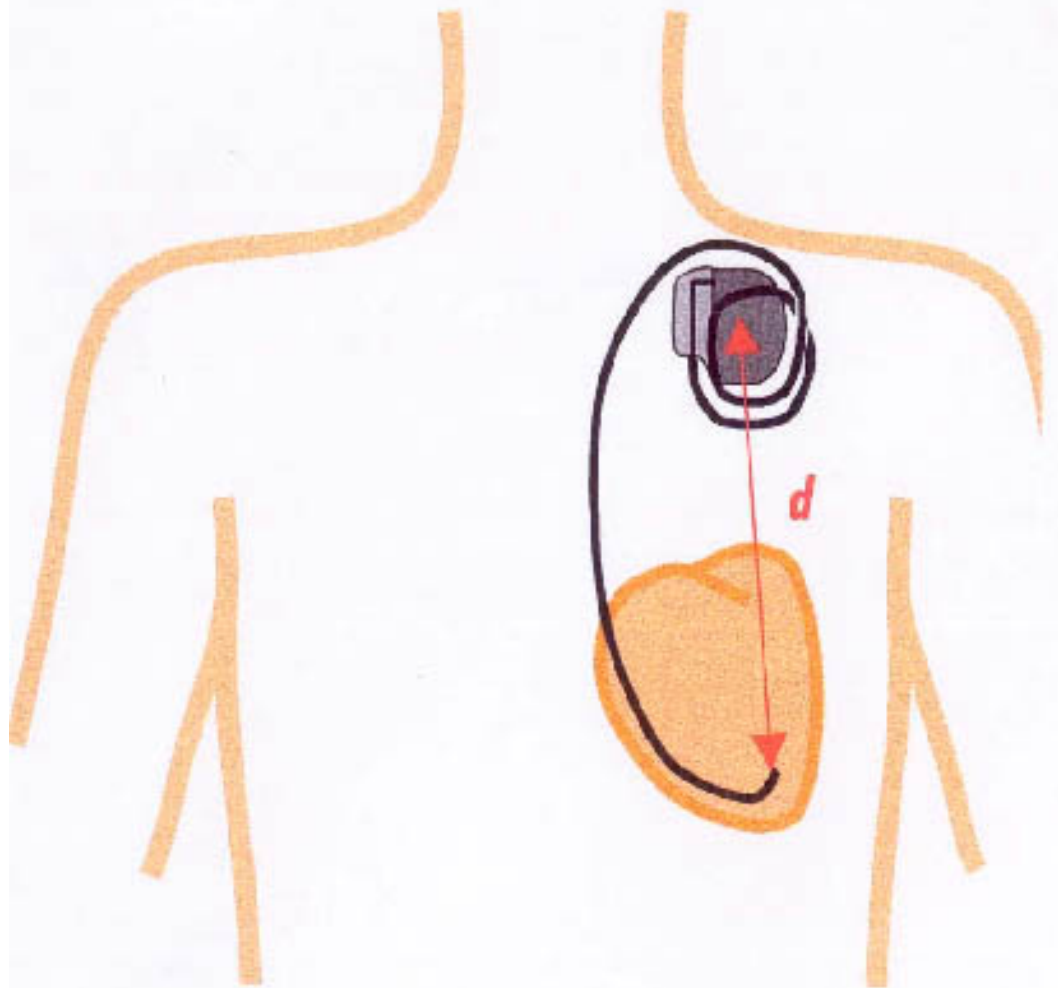
1. Basic pacemaker device and system
2. EMI considerations and mitigation
3. Standards
4. Labeling and education
5. Medtronic systems that mitigate EMI effects

System: patient, physician, pacemaker or ICD, leads, programmer, home monitor and network

In clinic programmer



Implantable Cardioverter Defibrillator (ICD)



CareLink home monitor



Pacemaker



EMI Coupling

EMI Coupling is complex and varies with:

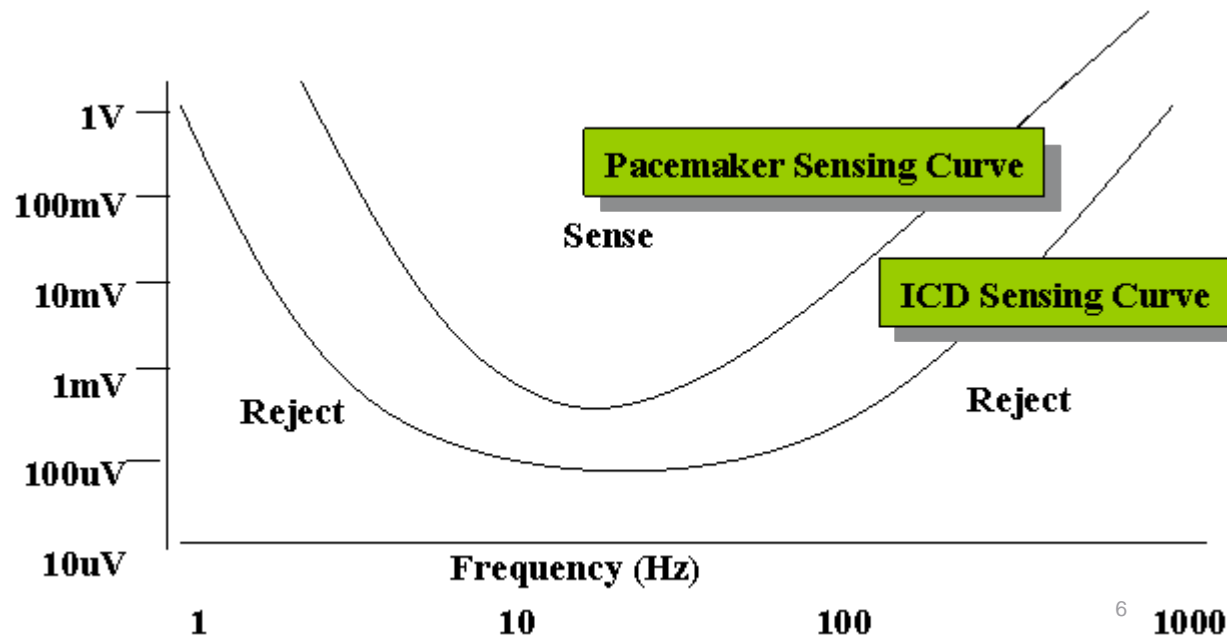
- electric or magnetic field E or H
- amplitude (or power)
- frequency
- modulation
- orientation of field
- duration

Potential Sources of EMI

- **Medical Procedures: Electrocautery, External Defibrillation, MRI, ...**
- **Radio Frequencies Transmitters**
- **Electronic Article Surveillance (EAS) Systems**
- **RFID**
- **Power Lines and Equipment that Generate Electric and Magnetic Fields at 60 and 50 Hz including contact current**
- **Arc welding**
- **Chainsaw operation**

Sensitivity

- **Input sense amplifier “bandpass”** from approx 10 Hz – 300 Hz
 - Based on the frequency content of the physiological signal
- **Sensing threshold :**
 - Sensitivity range: 0.15 - 2.1 mV for ICDs
 - Sensitivity range: 0.18 - 11 mV for pacemakers



Mitigating EMI

Shielding:

- Titanium housing - electric fields above ~2MHz
- Body tissues - High f shielding and leads in conductive medium are poor antennas

Filtration:

- Internal low pass filters
- Integrated feedthrough filters
- Characteristics of the bandpass

Algorithms

- Reversion circuit - proprietary noise rejection
- Proprietary timing algorithms
- Conversion to asynchronous pacing
- Proprietary detection algorithms

Proactive look-ahead to new technologies

Examples:

- Cordless Power
- mm-wave scanners
- Electric cars
- Medical technologies

International Technology Roadmap for Semiconductors

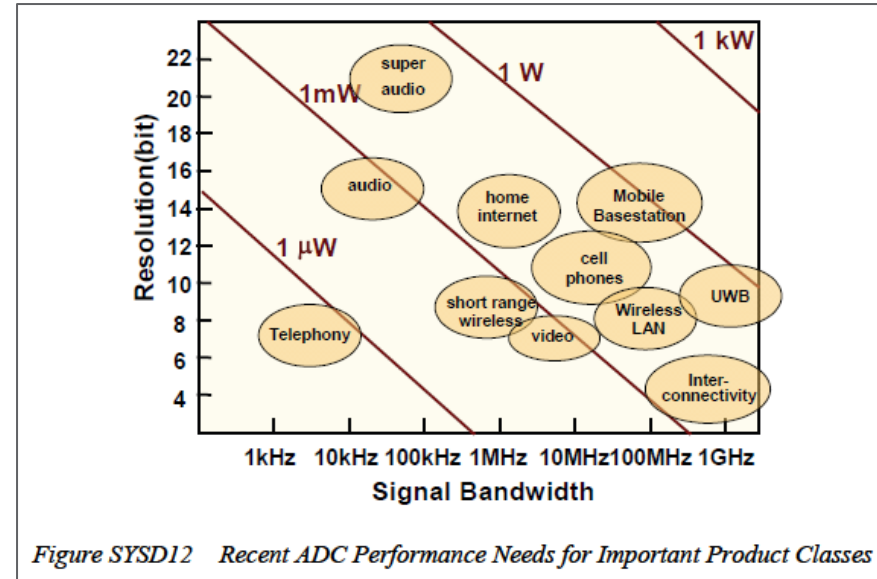


Figure SYSD12 Recent ADC Performance Needs for Important Product Classes

■ ■ ■

Working with other industries: RFID examples

Joint collaboration between medical device manufacturers, RFID manufacturers, and the FDA driven by PC-69 working group

Reference: HRTM 3665 – September 2009

In Vitro Tests Reveal Sample Radio Frequency Identification Readers Inducing Clinically Significant Electromagnetic Interference to Implantable Pacemakers and Implantable Cardioverter Defibrillators

Authors

Seth J. Seidman MS, U.S. Food and Drug Administration

Randall Brockman, MD, U.S. Food and Drug Administration

Brian Marc Lewis, MD, U.S. Food and Drug Administration

Joshua Guag, BS, U.S. Food and Drug Administration

Mitchell J. Shein, MS, U.S. Food and Drug Administration

Wesley J. Clement BS, Medtronic Inc

James Kippola BS, Boston Scientific

Dennis Digby BS, Biotronik

Catherine Barber MS, St Jude Medical

Dan Huntwork MS, Sorin

Joint collaboration between Medtronic and the RFID manufacturer Skidata



Skidata RFID Gate for Ski Resort Access Control

Some EMC Standards

CENELEC EN 45502-2-1 and -2

- Include EMC requirements from 0 Hz to 3,000 MHz

ANSI/AAMI PC69

- Active Implantable Medical Devices -Electromagnetic Compatibility - EMC Test Protocols for Implantable Cardiac Pacemakers and Implantable Cardioverter Defibrillators

+ RTTE standards

Labeling and Customer Education

Includes device manuals, stickers and symbols on packaging, customer pamphlets,

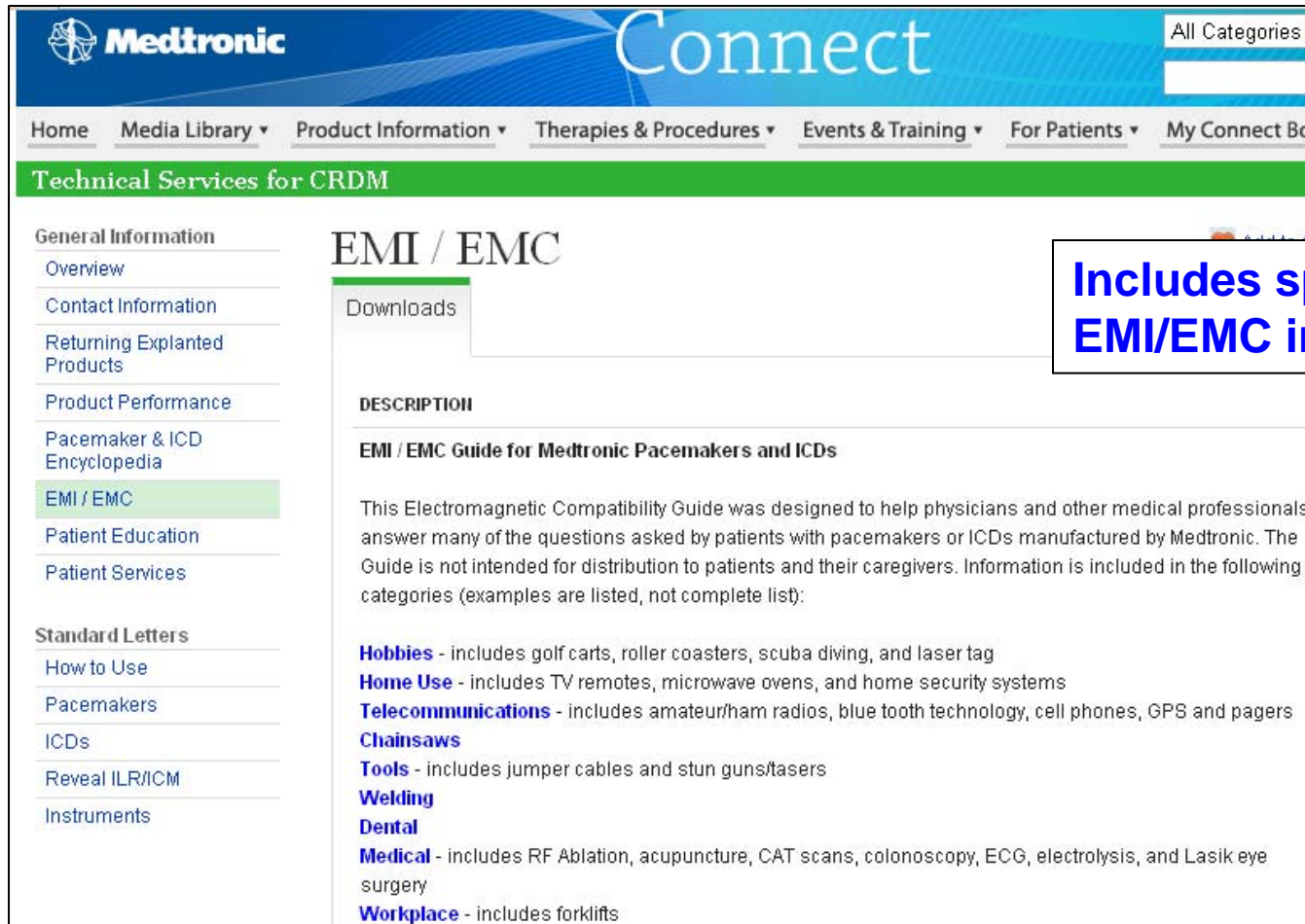
Examples:

- **Keep cell phones at least 15 cm from the implant**
 - Some older or European models may be susceptible
- **When exiting retail stores through security scanners
“Don’t Lean and Don’t Linger”**
- **Show airport security the ID card; ask for alternative search**

Medtronic Technical Services

Website and phone bank professionally staffed for medical professionals

- Questions and feedback
- Standard letters -- i.e. arc welding, security gates, electrosurgery, ...
- Connection to engineering
- Complaint portal



The screenshot shows the Medtronic Connect website interface. At the top, there is a blue header with the Medtronic logo and the word "Connect" in large white letters. Below the header is a navigation menu with links for Home, Media Library, Product Information, Therapies & Procedures, Events & Training, For Patients, and My Connect Box. A green banner below the navigation menu reads "Technical Services for CRDM". On the left side, there is a sidebar menu with categories like General Information, Standard Letters, and Patient Services. The "EMI / EMC" category is highlighted in green. The main content area displays the "EMI / EMC" page, which includes a "Downloads" tab and a "DESCRIPTION" section. The description is titled "EMI / EMC Guide for Medtronic Pacemakers and ICDs" and provides information about the guide's purpose and categories. A blue callout box on the right side of the page points to the "EMI / EMC" link in the sidebar menu, stating "Includes specific EMI/EMC info page".

Medtronic Connect

All Categories

Home Media Library Product Information Therapies & Procedures Events & Training For Patients My Connect Box

Technical Services for CRDM

General Information

- Overview
- Contact Information
- Returning Explanted Products
- Product Performance
- Pacemaker & ICD Encyclopedia
- EMI / EMC**
- Patient Education
- Patient Services

Standard Letters

- How to Use
- Pacemakers
- ICDs
- Reveal ILR/ICM
- Instruments

EMI / EMC

Downloads

DESCRIPTION

EMI / EMC Guide for Medtronic Pacemakers and ICDs

This Electromagnetic Compatibility Guide was designed to help physicians and other medical professionals answer many of the questions asked by patients with pacemakers or ICDs manufactured by Medtronic. The Guide is not intended for distribution to patients and their caregivers. Information is included in the following categories (examples are listed, not complete list):

- Hobbies** - includes golf carts, roller coasters, scuba diving, and laser tag
- Home Use** - includes TV remotes, microwave ovens, and home security systems
- Telecommunications** - includes amateur/ham radios, blue tooth technology, cell phones, GPS and pagers
- Chainsaws**
- Tools** - includes jumper cables and stun guns/tasers
- Welding**
- Dental**
- Medical** - includes RF Ablation, acupuncture, CAT scans, colonoscopy, ECG, electrolysis, and Lasik eye surgery
- Workplace** - includes forklifts

Includes specific
EMI/EMC info page

Medtronic Patient Services and Patient Education

Website and phone bank professionally staffed for patients

- Questions and feedback
- Complaint window

Education pamphlet specifically on EMI/EMC

No Known Risk	Minimal Risk	Special Considerations
<p>If the item is used as intended and in good working condition there is no known risk:</p> <ul style="list-style-type: none"> • Battery Charger – for household batteries • Casino Slot Machine • CD/DVD/VHS Player or Recorder • Dishwasher • Electric Blanket • Electric Guitar • Garage Door Opener • Heating Pad • Hot Tub • Ionized Air Filter • Iron • Kitchen Appliances – small and large (blender, can opener, refrigerator, stove, toaster) • Massage Chair/Pad • Medical Alert Necklace • Microwave Oven • Radio/iPod® • Remote Control (CD, DVD Player, TV, VHS) • Salon Hair Dryer • Shaver – battery powered • Tanning Bed • TV 	<p>Maintain at least a 6-inch distance between the item and your heart device:</p> <ul style="list-style-type: none"> • Cordless Headphone Sending Unit (TV/Stereo) • Cordless Telephone – from antenna and charging base • Electric Grocery Cart/Golf Cart – from motor • Electric Kitchen Appliances – hand-held (electric mixer or knife) • Electric Shaver – corded • Electric Toothbrush Charging Base • Hair Dryer – hand-held • Home Wireless Electronics – from antenna • Magnetic Therapy Products • Radio-controlled Items – from antenna • Sewing Machine/Serger – from motor • Small Magnet (household magnet) • Speakers • Treadmill – from motor • Vacuum Cleaner – from motor 	<p>Maintain at least the recommended distance between the item and your heart device:</p> <p>12-Inch Distance</p> <ul style="list-style-type: none"> • Car/Motorcycle – from components of ignition system • Electric Fence • Electric Pet Containment Fence – from buried wire and indoor antenna • Transformer Box (green box in yard) <p>2-Foot Distance</p> <ul style="list-style-type: none"> • Beach Comber Metal Detector – from search head • Induction Cooktop Stove <p>NOT RECOMMENDED</p> <ul style="list-style-type: none"> • Ab Stimulator • Electric Body Fat Scale • Magnetic Mattress Pad/Pillow

Specific EMI/EMC patient education pamphlet

Other systems impacting response

- CareLink Network
- Returned products analysis (~everything)
- Device Registry
- Robust Corrective and Preventative Action system
- Robust Risk Stratification
- Complaint tracking and reporting - trends, paretos, ...
- Tech Services, Patient Services, field representatives

Medical Device Industry Environment

Summary

- **Magnitude of any interaction depends on frequency, power, modulation, and duration**
- **Mitigate EMI through proactive design**
- **Tight feedback loop with field installation**
- **Medical device industry environment supports robust EMC**